K102716

SEP 28 2010

CONFIDENTIAL

Appendix 7 – 510(k) Summary for Modified Alma Lasers Family of Soprano™ Diode Laser Systems [Soprano, Soprano XLi]

Summary Preparation Date: September 15, 2010

- **General Information**

Sponsor/ 510(k) Owner Address and Establishment Registration #	**Sponsor**		
	Alma Lasers, Inc. 485 Half Day Rd. Suite No. 100 Buffalo Grove, IL 60089, USA FDA Registration #: 3004167969		
	Tatiana Epstein VP QA&RA Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 tatianae@almalasers.com
Contact Person:	Main Contact: Tatiana Epstein VP QA&RA Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 tatianae@almalasers.com
	Secondary Contact: Avi Farbstein EVP and GM North America Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 Avi.Farbstein@almalasers.com

- **Names**

  Device Names: Modified Alma Lasers Family of Soprano XL™ Multi-Application Platforms [Soprano XL, Soprano XLi]

  Primary Classification Names: Laser Instrument, Surgical, Powered; GEX Lamp, Infrared, Therapeutic Heating

- **Predicate Devices**
  - Soprano Hair Removal Diode Laser system (K052874), cleared 11/22/2005,
  - Alma Lasers Soprano XL Multi-Application Platform (K083848), cleared 04/14/2009
  - Alma Lasers NIR Module (K080318), cleared 03/07/2008,

- **Product Description**

  The Alma Lasers Soprano XLi system is a multi-application, multi-technology platform that supports the following technologies:
  - Diode laser technology
  - Near-infrared light technology (**NIR**)[5].

  The Soprano XLi **Diode Laser Module** is intended for hair removal and long-term hair reduction, as well as for the treatment of benign vascular and pigmented lesions.
  The Soprano XL system is indicated for use on all skin types (Fitzpatrick Skin Types I-VI), including tanned skin.
  The Soprano XLi **NIR Module** is indicated to elevate the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of

[5] The Alma Lasers NIR Module is separately cleared under K080318.

minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

The complete Soprano XLi platform consists of its console, two available module handpieces and a footswitch (refer to Figure 1). The module is pressed against the patient's skin and a light pulse is delivered when the handpiece trigger and/or the footswitch are activated. The handpiece tip is cooled to provide active and continuous skin cooling.
Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system micro-controller through an LCD touch-screen.

- **Indications for Use**

The Modified Alma Lasers Family of SOPRANO XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] is intended for use in dermatologic and general surgical procedures.
The Alma Lasers Family of SOPRANO XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] includes a Diode Laser Module and an optional NIR Module.

The Diode Laser Module:
The HR Mode is intended for hair removal, permanent hair reduction.
The LaserBlanche Mode is intended for the treatment of benign vascular and pigmented lesions.

The NIR Module is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
The Modified Alma Lasers Family of Soprano™ Diode Laser Systems [Soprano XL, Soprano XLi] is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.
The intended use **is identical** to that previously cleared for the Soprano™ (K052874), Alma Lasers NIR Module (K080318) and Alma Lasers Soprano XL Multi-Application Platform (K083848).
The Indications for Use statement can be found in Appendix 4.

- **Rationale for Substantial Equivalence**

The Modified Alma Lasers Family of Soprano XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] has the following similarities to the previously cleared Soprano™ Hair Removal Diode Laser System (K052874), Alma Lasers NIR Module (K080318) and Alma Lasers Soprano XL Multi-Application Platform (K083848):

  - Has the same intended use and indications for use,
  - Uses the same operating principle (technology),
  - Incorporates the same basic design,
  - Incorporates the same materials,
  - Is packaged using the same materials and processes.

In summary, the Modified Alma Lasers Family of Soprano™ XL™ Multi-Application Platforms [Soprano XL, Soprano Xli] is substantially equivalent to the predicate devices.

- **Safety and Effectiveness Information**

  The review of the indications for use and technical characteristics provided demonstrates that the Modified Alma Lasers Family of Soprano XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] is substantially equivalent to the predicate devices.

- **Conclusion**

  Modified Alma Lasers Family of Soprano XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] was found to be substantially equivalent to the predicate Soprano Family systems and devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2010

Alma Lasers, Inc.
% Ms. Tatiana Epstein
Vice President, QA & RA
485 Half Day Road, Suite 100
Buffalo Grove, Illinois 60089

Re: K102716
Trade/Device Name: Modified Alma Lasers Family of Soprano XL™ Multi-Application Platforms
Regulation Number: 21 CFR 878.34810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 16, 2010
Received: September 21, 2010

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

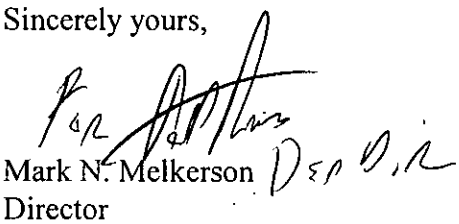
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102716
SEP 28 2010

510(k) Number (if known): K10

Device Name: **Modified Alma Lasers Family of Soprano™ Multi-Application Platforms [Soprano XL, Soprano XLi]**

Indications for Use:

The Modified Alma Lasers Family of SOPRANO XL™ Multi-Application Platforms [Soprano XL, Soprano XLi] is intended for use in dermatologic and general surgical procedures.

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102716